Frontalis Sling Operation using Silicone Rods in Comparison to Ptose-Up for Congenital Ptosis with Poor Levator Function

Syed Ziaeddin Tabatabaie, MD[1] • Arezou Momeni, MD[2] • Mohammad Taher Rajabi, MD[3]
Mohammad Zarei, MD[2] • Ali Izadi, MD[2] • Mohammad Bagher Rajabi, MD[2]

Abstract

***Purpose*:** To compare the cosmetic and functional results of frontalis sling procedure using silicone rod with polytetrafluoroethylene (Ptose-up) in congenital ptosis with poor levator function (LF)

***Methods*:** In a prospective randomized study, 90 eyes of 66 patients with congenital ptosis that underwent frontalis suspension surgery [31 patients (18 unilateral, 13 bilateral cases) using a silicone rod and 35 patients (24 unilateral, 11 bilateral cases) using Ptose-up] were included. Follow-up time was 6 months. The preoperative and postoperative medical records and photographs of patients and also their satisfaction were evaluated.

***Results*:** The functional success rate was not significantly different between the two groups (P>0.05), but silicone material extrusion and infection was more frequent (although statistically nonsignificant) in silicone rods group. The mean margin reflex distance (MRD_1) at 1, 3, and 6 months was 3.07 mm, 2.90 mm, and 2.61 mm in the silicone rods group, compared to 2.54 mm, 2.37 mm, and 2.37 mm in Ptose-up group. The results were significantly different between the two groups at one and 3 months (P=0.018, 0.012, respectively), but at 6 months the difference was not significant. The patients' satisfaction with the operation was significantly better in Ptose-up group compared to silicone rods group [42%: good, 45%: moderate, 13% poor; and 71%: good, 14%: moderate, and 14%: poor, respectively (P=0.017)].

***Conclusion*:** Ptose-up is an excellent alternative to the silicone rod for the sling procedure, with a good success rate and acceptable complication rates compared to the silicone rod, and better subjective satisfaction of the patients.

***Keywords*:** Ptosis, Poor Levator Function, Silicone Rod, Ptose-Up

Iranian Journal of Ophthalmology 2012;24(1):3-10 © 2012 by the Iranian Society of Ophthalmology

1. Associate Professor of Ophthalmology, Eye Research Center, Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran
2. Resident in Ophthalmology, Eye Research Center, Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran
3. Assistant Professor of Ophthalmology, Eye Research Center, Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran

Received: August 4, 2011
Accepted: December 29, 2011

Correspondence to: *Mohammad Taher Rajabi, MD*
Assistant Professor of Ophthalmology, Eye Research Center, Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran, Email: mt_rajabi@yahoo.com

Authors declare any financial support or relationships that may pose conflict of interest.
This manuscript data has been applied with taking informed consent from patients.

Introduction

Blepharoptosis is drooping of the upper eyelid. The ophthalmologist must assess visual function in congenital ptosis. If occlusion of pupil presents with congenital ptosis, surgical intervention should be considered as soon as possible. Frontalis suspension is the best procedure for congenital ptosis with poor levator function (LF) (less than 4 mm).[1]

There are various materials and techniques for sling procedure; synthetic products such as silicone rods, mersilene mesh, polytetrafluoroethylene (here called Ptose-up), and grafts such as fascia lata.[2] Fresh autogenous fascia lata has superior results, but harvesting the grafts is difficult compared to using synthetic materials. However, some studies have shown that silicone rod and mersilene mesh to be as effective as facsia lata and even superior in cosmetic results for sling procedure.[3,4]

In this study, we evaluate and compare the functional and cosmetic results and also patients' satisfaction of two synthetic materials; the silicone rod and Ptose-up (FCI Ophthalmics, Marshfield Hills, MA, USA). As far as we know such study has not been done yet.

Methods

In a prospective study between August 1, 2008 to September 1, 2009, 66 patients (90 eyes) with congenital ptosis with poor LF (less than 4 mm) who were found to be potential candidates for sling procedure were included in the study. Patients were randomly divided in 2 groups for alternate surgical plans including sling with application of silicone rod or sling with application of Ptose-up. Patients with blepharophymosis, Marcus gun jaw-winking ptosis, patients with history of other ocular or orbital surgery, and cases that were not followed up for at least 6 months were excluded.

This study was performed following the tenets of Declaration of Helsinki, and after approval by the Institutional Review Board of Tehran University Eye Research Center. Before randomization, the type of procedure and the implant used, the characteristics, and benefits of each operation were explained to the patients. Upon agreement to be studied and after taking informed consent, the patients were randomly assigned to the study groups.

Ptose-up is a strip of biomaterial made of expanded Poly Tetra Fluoro Ethylene (ePTFE) used to join the upper eyelid to the frontalis muscle in ptosis surgery with frontalis suspension. The strips are made of a biocompatible, porous, inert, biointegratable, nontoxic, nonallergenic material. After several weeks this biomaterial is integrated by cells.

Age, sex, LF, best corrected visual acuity (BCVA) , palpebral fissure, margin reflex distance (MRD_1), extraocular movement, slit-lamp exam, funduscopy, bell's phenomena, lid crease, complications (including exposure, granuloma, fistula, allergy to material, infection) were studied at baseline, one day, one week, three months, and six months follow-up visits. The measurements were obtained by one clinician and confirmed with photograph at each visit. Photographs were obtained while a tape is placed at the middle of glabella for a guideline to analysis.

Functional success rate was defined as eyelid above the papillary margin without serious complications resulting to reoperation.

Surgical procedure

In both silicone and Ptose-up group, surgery performed with pentagonal incisions (with base down) in the manner described by Simon et al[5] under general anesthesia. In summary two incisions were marked above the lid margin and three incisions were made in the brow. The wright needle and then silicone double rod were passed through the incisions. With pulling the rods and tightening the tie, eyelid level was adjusted to the superior limbus. The tie was secured with non-absorbable mersilene 5/0 suture and buried under the frontalis pocket. In the Ptose-up group, the same technique was used. After the operation, nonpreserved artificial tear was prescribed every two hours for 2 weeks and lubricating ointment at bedtime was ordered then for the interval adjusted to the postoperative complications such as exposure and red eye. Eyelid heights, lid crease, MRD_1, palpebral fissure size in downgaze, were calculated from photographs confirmed by direct measurement by one clinician. All patients or parents were asked if they were satisfied with the surgical outcome. We compared two groups' surgical results with

SPSS version 18 and P<0.05 was considered to be significant.

Results

Sixty-six patients (18 unilateral, 13 bilateral cases in silicone group and 24 unilateral and 11 bilateral cases in Ptose-up group) completed their data file. The demographic and preoperative data were summarized in table 1. There were 20 (64.4%) males in silicone group and 15 (42.9%) males in Ptose-up. Mean LF and mean MRD_1 were 3.36±2.49 mm, and -1±1.04 in silicone group, respectively and 3.74±2.09 mm and -1.2±0.88 in Ptose-up group. Mean palpebral fissure in primary and down gaze were 4.02 mm and 3.66 mm, respectively in silicone group, compared to 4.35 mm and 3.87 mm in the Ptose-up group. There were not significant differences between preoperative values (gender, age, laterality, MRD_1, palpebral fissure in primary and down gaze, presence of bell's phenomenon) between the two groups (Table 1).

Preoperatively, four (22%) unilateral cases and six (46.2%) bilateral cases had amblyopia in silicone group compared to 3 (12.5%) and 4 (36.4%) cases in the Ptose-up group. Two cases in silicone group had strabismus or limitation in ocular movement, but none of the cases in the other group. Two patients in silicone group had other ocular diseases and three in the other group. One case in silicone group had systemic disease in contrast to two cases in the Ptose-up group.

Postoperative MRD_1, palpebral fissure in primary and down gaze, and lid crease height are summarized in table 2. Postoperative MRD_1 values were different in two groups at 1 and 3 month (P=0.018 and 0.012, respectively). Overall MRD_1 values, palpebral fissure height in primary and down gaze were less in Ptose-up group compared to silicone group at all postoperative visits. Differences were statistically significant in early follow-up visits but at 6 month, there was no significant difference. The rate of decreases in MRD_1 from the operating time at 1, 3 and 6 month in two groups are summarized in table 3. Mean decrease was 0.61 mm, 1.0 mm, 1.21 mm, and 1.51 mm at one weak, one, three, and six months in silicone group compared to 0.59 mm, 1.26 mm, 1.43 mm, and 1.73 mm in Ptose-up group, respectively. There was no difference between the results obtained with the two materials used (P=0.89, 0.28, 0.29, and 0.76). Photographs of 2 patients that underwent sling procedure with application of silicone rod or ptose-up have been shown in figures 1 and 2.

Results for follow-up at 1, 3, and 6 months for asymmetry of lid and crease and for MRD_1 between the two groups are shown in table 4 for both the unilateral ptosis and bilateral ptosis (unilateral and bilateral cases analyzed and compared separately). The amount of asymmetry was not statistically different in the two groups (all P values>0.1).

Postoperative complications are summarized in table 5. Mild keratopathy (punctate epithelial keratitis involving only lower part of cornea) was seen in 9 cases of silicone eyes and 10 cases of Ptose-up group after one week. After one month, 8 cases of mild keratopathy developed in both groups and no case happened after three and six months in both groups. Moderate keratopathy (keratopathy involving whole of cornea) was observed in 2 cases of silicone group at one week and 3 cases at one month. Moderate keratopathy was not seen in Ptose-up group. Severe keratopathy (epithelial defect) was seen in one case of silicone group that did not respond to treatment and led to material removal before one month. Severe keratopathy was also seen in one case of Ptose-up that responded to lateral blepharorrhaphy plus aggressive lubrication.

One case of Ptose-up presented with severe lid edema and mild redness that did not respond to oral prednisolone and led to granuloma formation and material removal. One case of infection and fistula in both groups needed reoperation and material removal with reversal of ptosis after three months. At 6 months, two eyes in silicone groups developed material extrusion compared to no cases in the other group. Overall complications like material exposure seem to be less in Ptose-up group even though the difference was not statistically significant.

Postoperative success rate are summarized in table 6. There was no statistically difference between the 2 groups (all P>0.05). Patients' satisfaction is shown at Table 7. Overall, patients' satisfaction was

significantly higher for the Ptose-up group (P=0.017).

Table 1. The demographic and clinical characteristics of the patients with ptosis

	Silicone group	Ptose-up group	P
Patients[1]	44 eyes Unilateral (18) Bilateral (13)	46 eyes Nilateral (24) Bilateral (11)	0.33 0.66 0.25
Gender	20 Male (64.5%)	15 Male (42.9%)	0.09
Age	8.16±8.83 range 0.3 to 34 y	5.35±5.15 range1.1 to 28 y	0.12
Levator function	3.36±2.49	3.74±2.09	0.44
Margin reflex distance$_1$	-1.00±1.04	-1.20±0.88	0.31
Palpebral fissure (primary position)	4.02±1.24	4.35±0.95	0.16
Palpebral fissure (down gaze)	3.66±1.03	3.87±0.96	0.32
Bells phenomen	22 patients good (71%) bells	29 patients good (82.9%) bells	0.31

1: 66 patients (90 eyes)

Table 2. Postoperative finding of the groups at different follow-up

		Silicone		Ptose-up	P
Margin reflex distance$_1$	1w	4.12±1.04	1w	3.081.09	0.14
	1m	3.07±1.21	1m	2.54±0.89	0.018
	3m	2.90±1.08	3m	2.37±0.91	0.012
	6m	2.61±1.66	6m	2.37±0.93	0.27
Palpebral fissure (primary position)	1w	9.64±1.18	1w	9.04±1.30	0.03
	1m	8.53±1.61	1m	7.93±1.20	0.04
	3m	8.37±1.45	3m	7.61±1.29	0.01
	6m	8.05±1.78	6m	7.50±1.37	0.08
Palpebral fissure (down gaze)	1w	11.27±1.63	1w	10.46±1.67	0.021
	1m	9.21±1.70	1m	8.52±1.26	0.030
	3m	8.13±1.80	3m	7.76±1.30	0.026
	6m	7.11±2.00	6m	6.87±1.28	0.490
Lid crease	1w	3.75±0.77	1w	3.45±0.80	0.31
	1m	3.94±1.02	1m	3.54±0.87	0.04
	3m	4.15±1.12	3m	3.70±0.93	0.04
	6m	4.31±1.30	6m	3.96±1.07	0.16

Table 3. Amount of decrease in margin reflex distance with increasing time after surgery

	Silicone	Ptose-up	P
Decrease margin reflex distance$_1$ 1 week	-0.61±0.71	-0.59±1.02	0.89
Decrease margin reflex distance$_1$ 1 month	-1.00±0.95	-1.26±0.93	0.28
Decrease margin reflex distance$_1$ 3 Months	-1.21±0.91	-1.43±1.03	0.29
Decrease margin reflex distance$_1$ 6 months	-1.51±1.24	-1.73±1.17	0.76

Table 4. Lid crease and MRD_1 assymetry in groups after surgery

	e		Ptose-up		P	
	Unilateral	**Bilateral**	**Unilateral**	**Bilateral**	**Unilateral**	**Bilateral**
MRD_1 asymmetry 1 month	0.69±0.89	0.54±0.78	0.95±1.08	0.45±0.52	0.40	0.75
MRD_1 asymmetry 3 month	0.83±0.97	0.84±0.89	1.25±1.23	1.00±0.59	0.24	0.62
MRD_1 asymmetry 6 month	0.87±1.15	1.04±1.52	0.83±0.80	0.7±0.79	0.85	0.54
Crease asymmetry 1 month	2.44±0.46	0.30±0.48	2.21±1.37	0.36±0.45	0.59	0.77
Crease asymmetry 3 month	2.25±1.39	0.38±0.65	2.42±1.72	0.18±0.34	0.73	0.34
Crease asymmetry 6 month	2.00±1.28	0.61±1.12	2.00±1.64	0.36±0.45	0.50	0.46

Table 5. Postoperative complications

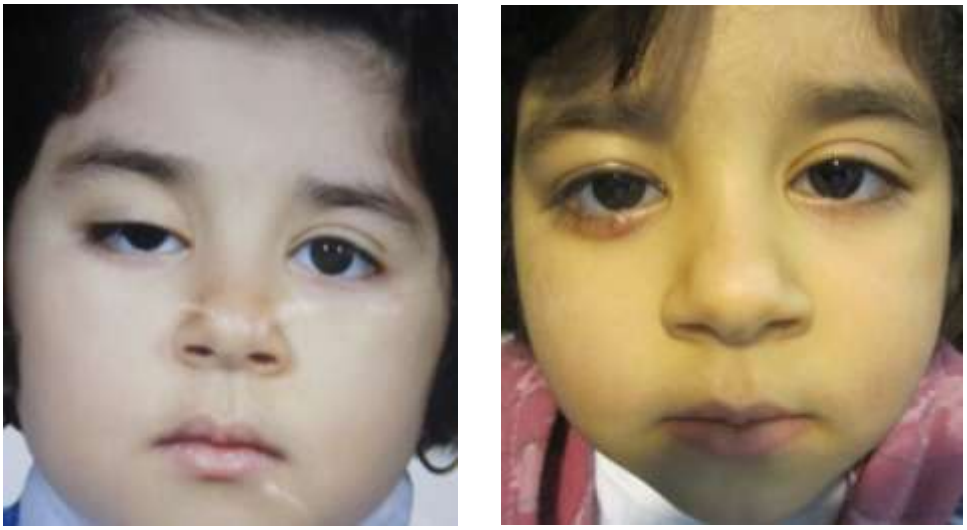
	Silicone complications	**Ptose-up complications**
1 week	9 mild keratopathy 2 moderate keratopathy 1 sever $keratopathy_1$	1 Allergic reaction to material[1] 10 mild keratopathy 1 sever keratopathy
1 month	8 mild keratopathy 3 moderate keratopathy	8 mild keratopathy
3 month	1 infection (fistula)	1 broken material[1]
6 month	1 exposed material 1 exposed & broken material	0

Table 6. Success rate in groups

	Silicone	**Ptose-up**
1 week	97.7%	97.83%
1 month	97.7%	97.83%
3 month	95.45%	95.65%
6 month	90.90%	95.65%

Table 7. Patients' satisfaction in groups

Satisfaction	**Silicone**	**Ptose-up**
Good	25 (71%)	13(42%)
Fair	5 (14%)	14(45%)
Poor	5 (14%)	4(13%)
P=0.017		



A B

Figure 1. A, B. Pre- and postoperative photograph of a patient that underwent sling procedure with application of Silicone rod

A B

Figure 2. A, B, pre- and postoperative photograph of a patient with right eye ptosis that underwent sling with application of Ptose-up

Discussion

Some studies have considered the use of synthetic materials for correction of ptosis as a temporary procedure because of the high rate of recurrences.[5-7] Silicone rod suspension surgery has been compared with fascia lata and some studies have shown better long-term results with the silicone rod procedure.[8,9] Carter and colleagues[9] reported the results of silicone rod suspension surgery as good as the other procedure and reported excellent results in all 35 patients enrolled in their study (61 eyes). Similarly, Kersten and colleagues[10] reported that final eyelid height was rated good to excellent in 39 of 41 patients who underwent the unilateral suspension procedure with Ptose-up; mean follow-up in their study was 11.6 months. Two patients in their study had exposed ptose-up that one of them required reoperation and sling removal.

This is the first study to compare silicone rod with Ptose-up, a competitive synthetic material for the frontalis suspension procedure. Ptose-up is a soft-tissue patch (a sheet of expanded Ptose-up. The porous material is intended to allow cellular

penetration of the tissue; however, silicone may be more elastic than Ptose-up.

The postsurgery results for this study show that MRD_1, palpebral fissure, and lid crease height are less prominent for the Ptose-up group at 1 month and 3 months; however, after 6 months the difference was not statistically significant. It seems that tissue embedding of Ptose-up and elastic property of silicone cause more stable results of Ptose-up than silicone during the study time. On the other hand, postoperative MRD_1 decreased with time on both groups, but this amount was not dependent on material. Lid lag was less in the Ptose-up group at 1 month, but the difference was not significant during the follow-up visits. During the follow-up at 1, 3, and 6 months, there were no significant differences in asymmetry of lid and crease between the two groups.

In recent studies it have been reported of a need for performing a second frontalis suspension with different materials in 7% to 32% of patients.[9-11] This is compared with a 9.1% incidence of reoperation in the silicone rod group and a 4.3% incidence in patients undergoing surgery with Ptose-up in our study at 6 months of follow-up. Some higher reoperation rates in other studies in part is probably due to the fact that in other studies the removal of material or adjustment (second surgery) was considered in the final tabulation of cosmetic results as well as functional results. In our study, only the functional success rate was considered in the determination of success.

We did consider severe complications as failures, including infection, lack of responsiveness to medication after severe keratopathy, and material exposure or breakdown. Complications were more frequent in the silicone group, even though the difference was not significant that may be due to a small sample size. Morax et al[12] cite a 10% extrusion rate for expanded Ptose-up at 3 months. Conversely, in our study we had no cases of Ptose-up extrusion; most likely because the ends of the material were buried sufficiently deep during brow incision. One case manifested allergy/hypersensitivity reaction to the material; this patient did not respond to medical treatment and needed reoperation because of the granuloma formation. Some reports have indicated that synthetic materials are more prone to cause infection and granuloma formation.[13,14] Lee and colleagues[4] reported on 60 patients undergoing silicone rod suspension surgery and stated that no serious complications such as infections or granulomas occurred. In the present study, we had 2 cases with silicone extrusion and one with infection; the infection may be attributable to the thicker tie in silicone, which makes the meticulous burying of the tie and skin repair more difficult and consequently causing this complication.

Patients' satisfaction in the silicone group were similar to those of Lelli and colleagues,[8] who reported patient evaluations of good ($^{28}/_{51}$), acceptable ($^{17}/_{51}$) and poor ($^{6}/_{51}$) for frontalis suspension. Overall, patient satisfaction was significantly higher for the Ptose-up group.

There are some limitation for this study such as small sample size and short follow-up period.

Conclusion

In conclusion, Ptose-up is an excellent alternative to silicone rod for sling procedure. Ptose-up is as effective as silicone for correction of congenital ptosis caused by poor LF, and has fewer complications (such as material extrusion at 6-month follow-up) than silicone. Therefore, Ptose-up had a superior functional success rate. Patients' subjective satisfaction with the surgery was also higher with Ptose-up.

References

1. Yoon JS, Lee SY. Long-term functional and cosmetic outcomes after frontalis suspension using autogenous fascia lata for pediatric congenital ptosis. Ophthalmology 2009;116(7):1405-14.
2. Sternberg I, Seelenfreund MH, Stenberg N. A new sling material for ptosis patients. Ophthalmic Surg 1988;19(1):64-6.

3. Downes RN, Collin JR. The Mersilene mesh sling--a new concept in ptosis surgery. Br J Ophthalmol 1989;73(7):498-501.
4. Lee MJ, Oh JY, Choung HK, et al. Frontalis sling operation using silicone rod compared with preserved fascia lata for congenital ptosis a three-year follow-up study. Ophthalmology 2009;116(1):123-9.
5. Ben Simon GJ, Macedo AA, Schwarcz RM, et al. Frontalis suspension for upper eyelid ptosis: evaluation of different surgical designs and suture material. AM J Ophthalmol 2005;140(5):877-85.
6. Wagner RS, Mauriello JA Jr, Nelson LB, et al. Treatment of congenital ptosis with frontalis suspension: a comparison of suspensory material. Ophthalmology 1984;91(3):245-8.
7. Wasserman BN, Sprunger DT, Helveston EM. Comparison of materials used in frontalis suspension. Arch Ophthalmol 2001;119(5):689-91.
8. Lelli GJ Jr, Musch DC, Frueh BR, Nelson CC. Outcome in silicone rod frontalis suspension surgery for high-risk noncongenital blepharoptosis. Ophthal Plast Reconstr Surg 2009;25(5):361-5.
9. Carter SR, Meecham WJ, Seiff SR. Silicone frontalis slings for the correction of blepharoptosis: indications and efficacy. Ophthalmology 1996;103(4):623-30.
10. Kersten RC, Bernardini FP, Khouri L, et al. Unilateral frontalis sling for the surgical correction of unilateral poor-function ptosis. Ophthal Plast Reconstr Surg 2005;21(6):412-7.
11. Leone CR Jr, Shore JW, Van Gemret JV. Silicone rod frontalis sling for correction of blepharoptosis. Ophthalmic Surg 1981;12(12):881-7.
12. Morax S, Bok C, Ruban JM. [Use of Gore-Tex (PTFE) in ophthalmic plastic surgery]. Ophtalmologie 1987;1(4):493-5.
13. Goldberger S, Conn H, Lemor M. Double rhomboid silicone rod frontalis suspension. Ophthal Plast Reconstr Surg 1991;7(1):48-53.
14. Manners RM, Tyers AG, Morris RJ. The use of Prolene as a temporary suspensory material for brow suspension in young children. Eye (Lond) 1994;8(Pt 3):346-8.